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Paper 12
Date: January 9, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION AND EDWARDS LIFESCIENCES LLC,
Petitioner,

v.

AORTIC INNOVATIONS LLC,
Patent Owner.

IPR2023-01151
Patent 11,337,834 B2

Before JOHN G. NEW, RYAN H. FLAX, and TIMOTHY G. MAJORS, *Administrative Patent Judges.*

MAJORS, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Edwards Lifesciences Corp. and Edwards Lifesciences LLC (collectively "Petitioner") filed a Petition (Paper 1, "Pet") requesting *inter partes* review of claims 1–6 and 8–18 of U.S. Patent No. 11,337,834 B2 (Ex. 1001, "the '834 patent"). Pet. 1, 19. Aortic Innovation LLC ("Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp."). Petitioner also filed a Preliminary Reply (Paper 9) and Patent Owner filed a Preliminary Sur-reply (Paper 11), both papers providing further argument and evidence about the "spacing" claim limitation, which we discuss below.

Patent Owner has since disclaimed claims 1, 3–6, 8, and 10–16 of the '834 patent. *See* Ex. 2135; Prelim. Resp. 78–79; 35 U.S.C. § 253(a). *Inter partes* review may not be ordered for the disclaimed claims. *See* 37 C.F.R. § 42.107(e) ("No *inter partes* review will be instituted on disclaimed claims."); *Vectra Fitness, Inc. v. TWNK Corp.*, 162 F.3d 1379, 1383 (Fed. Cir. 1998) ("This court has interpreted the term 'considered as part of the original patent' in section 253 to mean that the patent is treated as though the disclaimed claims never existed."). Of the challenged claims, that leaves claims 2, 9, 17, and 18 remaining.

Under 35 U.S.C. § 314(a), *inter partes* review may not be instituted unless the Petition "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." For reasons discussed below, we do not institute review of claims 2, 9, 17, and 18 of the '834 patent.

II. BACKGROUND

A. Real Parties-in-Interest

Petitioner identifies Edwards Lifesciences Corp. and Edwards Lifesciences LLC as the real parties-in-interest. Pet. 100. Patent Owner identifies itself as the real party-in-interest. Paper 5, 1.

B. Related Matters

The parties identify the following lawsuit involving assertion of the '843 patent (along with other asserted patents): *Aortic Innovations LLC v. Edwards Lifesciences Corp.*, 23-cv-00158 (D. Del.); Pet. 101; Paper 5, 1.

Petitioner also identifies related matters before the Board involving the same parties and related patents. Pet. 100–101. Those matters include: IPR2021-01527; IPR2021-01584; IPR2022-00193; IPR2022-00034; IPR2022-00556; and IPR2022-00549. *Id.*; *see also id.* at 6–8 (identifying the earlier-filed IPRs and their status).[1]

C. The '834 Patent

The '834 patent is entitled "Transcatheter Aortic Valve Repair Having Improved Paravalvular Seal." Ex. 1001, code (54). The '834 patent issued from U.S. Application No. 17/327,673, filed May 22, 2021, which claims priority through a series of related applications. *Id.* at codes (21), (22), (63). The earliest applications in the '834 patent's identified priority chain are two U.S. provisional applications filed November 7, 2012, and December 6, 2011. *Id.* at code (60).

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[1] In final written decisions, the Board determined that all challenged claims were unpatentable in the 1527 and 1584 cases and that some challenged claims were unpatentable in the 0193 case. Exs. 1117, 1118, 1119. The Board concluded that no challenged claims were proved unpatentable in the 0034 and 0556 cases, and the Board denied institution in the 0549 case. Exs. 1120, 1121, 2124.

According to the '834 patent, none of the devices in clinical use for endovascular repair of ascending aortic aneurysms "have been designed with the purpose of endovascular repair of multiple types of ascending aortic aneurysms." *Id.* at 2:40–44.

The patent describes a need for a device

> that can treat different anatomical variations of ascending aortic aneurysms, create effective proximal and distal seal zones within the aorta, and have a durable valve component, but that also allows for future valve re-interventions. A device is also needed that would allow for treatment of different coronary anatomical variations among the patient population, allow future coronary re-intervention, but that also avoids coronary compression, and enables treatment of possible paravalvular leaks.

Id. at 2:44–53.

The '834 patent discloses an endograft device, including a transcatheter heart valve for endovascular repair of ascending aortic aneurysms. Ex. 1001, 2:57–59. The patent discloses that the device includes first and second prosthetic components, in which the first prosthetic component has a proximal frame and the second prosthetic component is secured to the first prosthetic component. *Id.* at 2:59–67. "The endograft device also includes a valve element that is secured to [a] balloon-expandable frame at the proximal end of the second prosthetic component." *Id.* at 3:5–7. Moreover, the second prosthetic component may include "a self-expanding frame that is connected to the balloon-expandable frame." *Id.* at 2:67–3:4.

Figure 11 of the '834 patent is reproduced below.

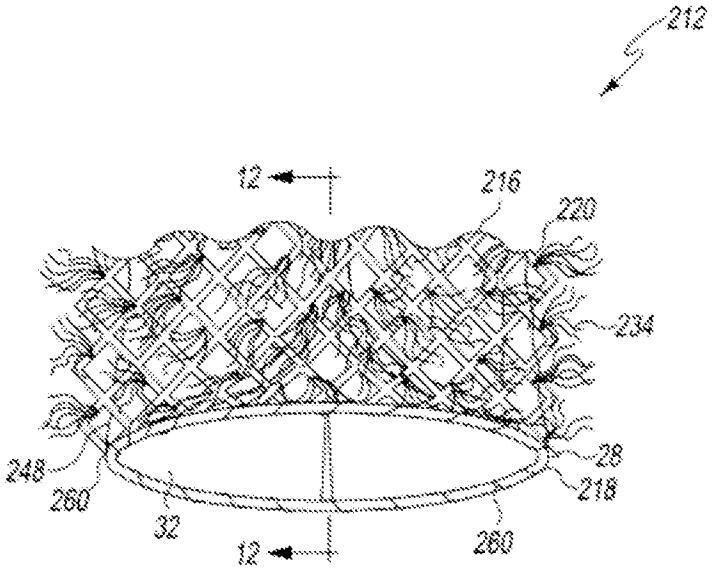


Fig. 11

Id. at Fig. 11. Figure 11, as shown above, is a perspective view of a proximal end of the proximal prosthetic component 212 of the endovascular device. *Id.* at 5:58–59. Figure 11 shows the prosthetic component with an outer "self-expanding" frame 216 and an inner frame 218 and valve component 32 disposed within the outer frame 216. *Id.* at 14:16–23. Figure 11 also shows fibers 234 attached to the outer frame 216. *Id.*

Figure 13 of the '834 patent is reproduced below.

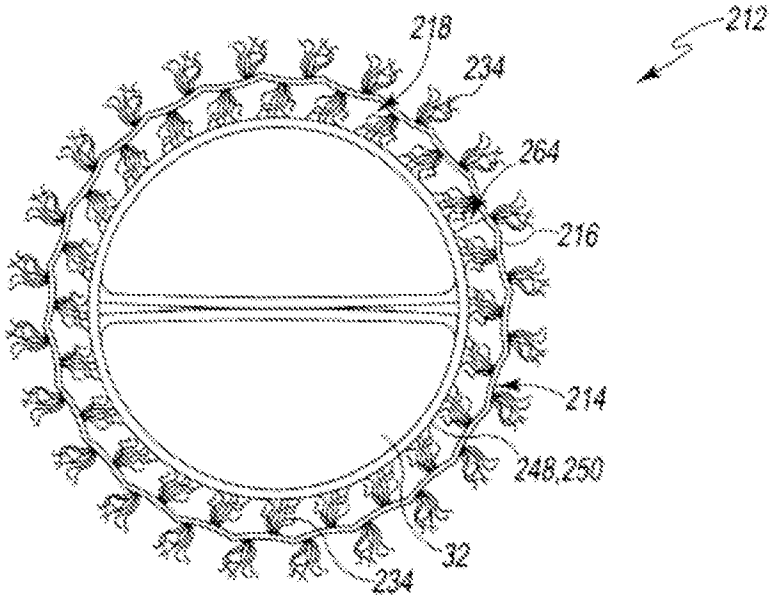


Fig. 13

Id. at Fig. 13. Figure 13 is a longitudinal view of the proximal prosthetic component 212, again including outer frame 216, inner frame 218, and valve component 32, with the inner frame shown in an unexpanded state. *Id.* at 5:63–65. Figure 13 shows pluralities of fibers 234 attached to the outer frame—some fibers extending outwardly and some fibers extending inwardly from that frame. *Id.* at 14:24–26. In the unexpanded state, a gap 264 is defined between the inner and outer frames. *Id.* at 14:24–28.

The '834 patent discloses that the "[b]alloon-expandable frame 218" may be embodied as a "balloon-expandable tubular stent 244." Ex. 1001, 13:51–53. "[S]tent 244 is tubular and is constructed of a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material, in an opencell configuration." *Id.* at 13:56–58. "When the inner frame 218 is unexpanded, the outer surface 248 of the stent 244 is spaced apart from the fibers 234 attached to the outer frame 216." *Id.* at Fig. 13, 14:24–26. When inner frame 218 is expanded, outer surface 248 of stent 244 engages fibers

234 through covering material 250, thereby closing gap 264 so that fibers 234 and covering material 250 create a seal between inner frame 218 and outer frame 216. *Id.* at Figs. 13, 14 (view in expanded state), 14:29–42.

Moreover, expansion of the balloon-expandable inner frame 218 engages the inner frame 218 with the outer frame 216, compressing the fiber-coated proximal section 220 of the outer frame 216 against the patient's aortic annulus. *Id.* at 15:1–7 (disclosing that the combined engagement of the frames seals the annulus and prevents paravalvular leakage). According to the '834 patent, in embodiments, fibers 234 attached to the proximal section 220 aid in preventing paravalvular leaks and valve migration within the aortic walls. *Id.* at 18:34–37.

D. Illustrative Claims

Dependent claim 2, reproduced below, is illustrative of the challenged claims. Claim 1 (now disclaimed), from which claim 2 depends, is reproduced below followed by claim 2:

> 1. An endovascular prosthetic heart valve for use in a patient, comprising:
>
> a frame formed of a plurality of struts that cooperate to form a plurality of cells,
>
> wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;
>
> a leaflet assembly within the frame;
>
> a polymer covering, wherein the polymer covering is attached to the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;
>
> a first plurality of fibers that extend away from the frame, wherein the prosthetic heart valve is endovascularly deployed through a femoral artery of the patient,
>
> wherein the first plurality of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient;

> a second plurality of fibers that is positioned radially inwardly from the first plurality of fibers,
>
> wherein the second plurality of fibers is in direct contact with the frame.

Ex. 1001, 21:28–51.

Claim 2 reads as follows:

> 2. The prosthetic heart valve of claim 1, wherein the second plurality of fibers defines a spacing extending through a thickness thereof that is created by a distance between adjacent fibers, wherein the spacing extends to the frame.

Id. at 21:52–56.

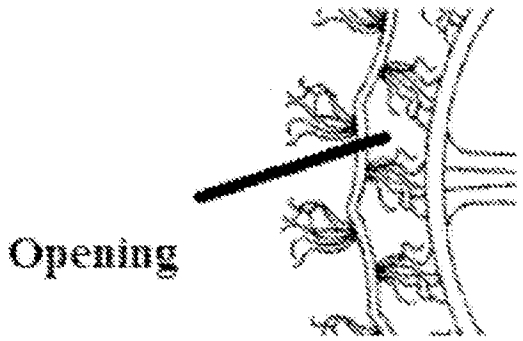
Claim 9 depends from claim 1 and adds that the heart valve is "free of a non-porous graft covering between the first plurality of fibers and the frame and the second plurality of fibers and the frame." *Id.* at 22:9–12.

E. Prosecution History

The application that matured into the '834 patent was filed on May 22, 2021. Ex. 1001, code (22). During prosecution, applicant submitted preliminary and supplemental amendments, canceling application claims 1–10, adding new application claims 11–26, and amending language in claim 11 (corresponding to issued claim 1). Ex. 1002, 1254–1258 (Supplemental Amendment dated July 27, 2021, amending claim 11 to add language about "a second plurality of fibers" and their positioning; canceling application claim 12), 1280–1283. At that time, application claim 13 (corresponding to issued claim 2) required that "the second plurality of fibers defines an ***opening*** extending through a thickness thereof that is created by spacing formed between adjacent fibers, wherein the opening extends to the frame." *Id.* at 1255 (emphasis added).

On August 11, 2021, the Examiner rejected the claims under 35 U.S.C. § 112 for lack of written description and for indefiniteness. *Id.* at 1155–1161. In rejecting application claim 13 for lack of written description, the Examiner stated that "[i]t is unclear what 'opening' is being referred to, but it appears that this may be an attempt to refer to the gap between the inner and outer frames described in paragraph 91," and suggested that the applicant ensure that this subject matter is described in a manner consistent with the Specification. *Id.* at 1158, 1160 (advancing similar reasoning for the indefiniteness rejection).

In a response dated August 14, 2021, applicant further amended the claims and sought to traverse the above-noted § 112 rejections. *Id.* at 1124–1154. Concerning application claim 13, applicant provided an enlarged and annotated partial view of Figure 13, reproduced below.



Id. at 1133. The figure reproduced above is a partial view of Figure 13 of the Specification, with an annotation labeling a portion as an "Opening" and providing a line pointing between two outwardly-extending fiber clusters and into an area between the outer and inner frames. *Id.* With this annotation, applicant asserted that "[t]he advantage of this limitation is that the opening reduces restrictions on expansion and contraction of the stent frame (as opposed to a solid, outer graft), and encourages thrombos of the fibers by allowing blood flow therethrough." *Id.*; *see also id.* at 1139–1140

(asserting, for similar "openings" language in newly-added application claim 28 (issued claim 17) that the "advantage" of this claim feature is "the ability for thrombosis of the array of fibers about the frame to thereby seal the frame after compression of the fibers, while the lower overall fiber density of the claimed invention (as compared for example with a stent graft) allows for proper expansion of the valve" without disadvantages like an increased profile size).

In this same response, applicant provided a lengthy discussion about prior art valve technology, including publications by Levi and Spenser.[2] *See, e.g.*, *id.* at 1142–1145. Applicant asserted, for example, that "WO2006/005015 ('Spenser') appears to teach a thick band with fibers emanating therefrom in FIG. 22." *Id.* at 1144 (reproducing, e.g., Fig. 22 of Spenser II, and asserting that "[t]he thick outer seal of Spenser adds to valve profile size and restricts foreshortening").

Moreover, applicant asserted that at least one putatively non-prior art commercial product—the "Sapien 3 Ultra"—has adopted the technology covered by the claimed invention. *Id.* at 1152–1153 (asserting that "[t]he Sapien 3 Ultra sealing skirt appears to be covered by the claimed invention"). According to applicant, with the "Sapien 3 Ultra" valve, "there is a first array of fibers forming a mesh, and a second array of fibers that end

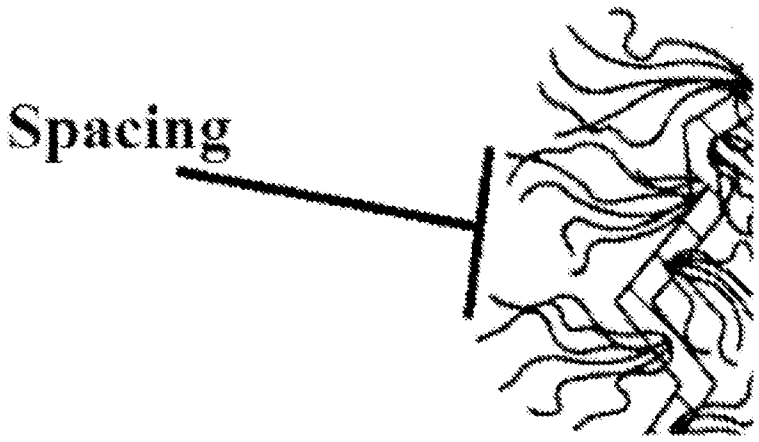
[2] "Spenser" referenced here in prosecution is the "Spenser II" reference asserted in this case, and Levi cited here in prosecution is the published application that later issued as the Levi patent asserted as prior art in this case. Ex. 1011; Ex. 1008, code (65). Applicant additionally asserted that the Spenser II valve (or a valve similar thereto) "appears to be shown in the NPL Walther" reference submitted in an Information Disclosure Statement. Ex. 1002, 1144 (comparing images of the Spenser II and Walther valves); *see also* Ex. 1007 ("Walther"), 1120–1121 (describing and depicting the "Edwards SAPIEN™ trans-catheter heart valve").

therefrom and into engagement with native leaflets of a patient." *Id.* (providing an image alleged to show a construction of and "openings" in the fiber materials of the Sapien 3 Ultra valve).

On September 2, 2021, the Examiner entered a final rejection, maintaining the written description and indefiniteness rejections. *Id.* at 1030–1035. The Examiner explained: "for claim 13, Applicant points to an 'opening' in an annotated figure. However, it seems to only be a spacing rather than an opening." *Id.* at 1032 (remarking that applicant did not provide citations to support the "advantage[s]" of this feature); *see also id.* 1034 ("The specification in the Figures appears to support a spacing but not an 'opening' formed by fibers between the spacing of the frame.").

Applicant responded on September 2, 2021, further amending the claims and arguing that the rejections should be withdrawn. *Id.* at 994–1003. Applicant amended application claim 13, deleting the "opening" language, and replacing it with "spacing" language. *Id.* at 995 (amending claim 13 as follows: "wherein the second [[array]] plurality of fibers defines ~~an opening~~ a spacing extending through a thickness thereof that is created by ~~spacing formed~~ a distance between adjacent fibers, wherein the ~~opening~~ spacing extends to the frame." (strikethrough and brackets showing deleted language and underlined text showing language that was added)); *see also id.* at 997–999 (showing similar amendments in application claims 28 and 29 (issued claims 17 and 18)).

At the same time, applicant argued "that the figures clearly display the 'spacings' limitations." *Id.* at 1000–1002 (highlighting MPEP provisions to the effect that drawings alone may provide sufficient written description support). Applicant also provided an annotated partial view of Figure 12 as reproduced below.



Id. at 1001–1002. The partial view of Figure 12 above shows a portion of an outer frame with multiple fiber clusters extending outwardly therefrom; the figure is annotated with the word "Spacing" and intersecting lines alleged to show this "spacing" feature in relation to the depicted fibers and frame. *Id.* Applicant argued that it "is describing the spacing that is caused by the distance between spaced-apart outwardly-extending fibers, and not the 'gap/spacing between the inner and outer frames,'" contrary to what the Examiner had suggested in an earlier Office Action. *Id.* at 1001 ("What the Applicant is claiming is the spacing between segments of some fibers," which "spacing allows for inward deflection and compression of the fibers when the frame is expanded to fill any voids within the annulus and the seal formed by the fibers.").

Continuing, applicant argued that the "spacing" feature as claimed is different than what the prior art taught. *Id.* More specifically, applicant stated: "Compare this [spacing feature] to a very tightly knitted outer seal made of tightly knitted fibers (such as found in NPL, Walther . . . or WIPO Publication 2006005015A2 to Spenser, [(i.e., Spenser II)] with reference to FIG. 22, . . . there the lack of 'spacings' between some fibers would not allow for compression of the outwardly extending fibers." *Id.* (asserting "the

spacing [like claimed] provides a lesser rigidity than a graft covering (as one example, a graft covering cannot foreshorten during crimping expansion to the same degree as a loosely defined fiber structure)").

On January 25, 2022, the Examiner allowed the pending claims. *Id.* at 845–851. In doing so, the Examiner made two substantive findings. First, the Examiner found that "the closest prior art does not disclose or render obvious a prosthetic heart valve [comprising] a second plurality of fibers that is positioned radially inwardly from the first plurality of fibers, wherein the second plurality of fibers [is] in direct contact with the frame." *Id.* at 850. Second, the Examiner found, "referring to claim 29 [(issued claim 18)], [t]he prior art does not disclose or render obvious the prosthetic heart valve defining a spacing extending through a thickness of the plurality of fibers that is created by a distance between adjacent fibers thereof through the plurality of cells of the frame." *Id.*

F. Prior Art and Asserted Grounds

Petitioner asserts that claims 2, 9, 17, and 18[3] are unpatentable based on the following grounds:

[3] As noted above, Patent Owner disclaimed challenged claims 1, 3–6, 8, and 10–16 after the Petition was filed. Ex. 2135 (Oct. 10, 2023, Disclaimer).

Claims Challenged	35 U.S.C. §[4]	References/Basis
2, 9, 17, 18	103	Spenser,[5] Spenser II[6]
2, 9, 17, 18	103	Levi,[7] Spenser II
2, 9, 17, 18	103	Spenser, Chuter[8]
2, 9, 17, 18	103	Levi, Chuter
2, 9, 17, 18	103	Spenser, Chuter, Spenser II
2, 9, 17, 18	103	Levi, Chuter, Spenser II

Petitioner relies on testimony from Nigel Buller, M.D., in support of its challenge. Ex. 1003 (Buller Decl.). In response, Patent Owner submits testimony from Stephen J.D. Brecker, M.D. Ex. 2002 (Brecker Decl.). The

[4] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, 125 Stat. 284, 285–88 (2011), revised 35 U.S.C. §§ 102, 103 effective March 16, 2013. Petitioner asserts that the critical date of the '834 patent is November 7, 2012. Pet. 19–20. Because that date precedes the effective date of the applicable AIA amendments, we apply the pre-AIA version of § 103 here.
[5] Spenser et al., US 7,510,575 B2, issued Mar. 31, 2009 (Ex. 1010 ("Spenser")).
[6] Spenser et al., WO 2006/005015 A2, pub. Jan. 12, 2006 (Ex. 1011 ("Spenser II")).
[7] Levi et al., US 9,393,110 B2, issued July 19, 2016, from an application filed Oct. 5, 2011 (Ex. 1008 ("Levi")).
[8] Chuter, US 2002/0151958 A1, pub. Oct. 17, 2002 (Ex. 1116 ("Chuter")).

parties additionally submit testimony from Drs. Buller and Brecker from related proceedings. *See supra* Section II(B).

III. ANALYSIS

A. Legal Standards

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3)).

A claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the relevant art. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective indicia (also called secondary considerations) of nonobviousness when presented.[9] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). Moreover, "[a]n obviousness determination requires finding both that a skilled artisan would have been motivated to combine the

[9] The parties did not present substantive argument on secondary considerations. Pet. 98 ("Petitioner is not aware of any evidence of secondary considerations"). Patent Owner mentions the Board's alleged "credit[ing]" of Dr. Brecker's testimony in related matters referencing an "unexpected result." Prelim. Resp. 5, 77 (citing Ex. 2124, 33–34). This overstates the Board's citation to a paragraph of testimony from Dr. Brecker, which the Board cited for a claim construction issue and, in no way, was this citation a finding that any unexpected result had been established. Ex. 2124, 33–34. Patent Owner, in any case, presents no argument on nexus issues.

teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *CRFD Rsch., Inc. v. Matal*, 876 F.3d 1330, 1340 (Fed. Cir. 2017) (internal quotation marks and citation omitted).

B. Level of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the problems encountered in the art, the art's solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986).

Petitioner proposes that the person of ordinary skill in the art ("POSA") in November 2012 "would have been an interventional cardiologist with a working knowledge of heart valve designs and endovascular prostheses. This [POSA] would, where necessary, work with a medical device engineer to experiment with or manufacture a prosthetic heart valve." Pet. 21 (citing Ex. 1003 ¶ 49). Patent Owner does not expressly contest Petitioner's proposed definition.

For this Decision, we apply Petitioner's proposed POSA level, which appears to be consistent with the level of skill shown in the prior art of record. *See Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007). This POSA level is also consistent with the level the Board applied in earlier decisions involving the same parties and related patents. *See, e.g.*, Ex. 2124, 11; Ex. 1120, 11–12.

C. Claim Construction

In *inter partes* review, we construe claims using the same claim construction standard used to construe claims in a civil action before the courts under 35 U.S.C. § 282(b), including construing claims' language in

accordance with its ordinary and customary meaning as understood by the POSA, in view of the patent's specification and considering the patent's prosecution history. 37 C.F.R. § 42.100(b). We need only construe terms that are in controversy and only as needed to resolve the matters in dispute. *Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019).

Petitioner contends that "[n]o terms of the '834 patent require construction to resolve the patentability issues herein." Pet. 21. Furthermore, according to Petitioner, its asserted unpatentability "grounds are based on [Patent Owner's] allegations that the '834 patent covers Petitioner's SAPIEN 3 Ultra valve and the scope of the claims asserted by [Patent Owner] in litigation." *Id.* (citing Ex. 1122 (Complaint); Ex. 1123 (Infringement Contentions), 2, 24–261).

Patent Owner contends that the Board should interpret certain claim terms consistent with the Board's or the district court's prior constructions. Prelim. Resp. 2–3. Specifically, Patent Owner asserts, the Board should follow the district court's decision and interpret the terms "frame" and "fibers" based on their "Plain and Ordinary Meaning." *Id.* (citing Ex. 2127,[10] 7, 22). Moreover, Patent Owner contends the term "outer graft covering" (appearing in claim 9) should be construed in the same way as in IPR2022-00556 and IPR2022-00034. *Id.* In those IPRs, the Board construed an "outer graft covering" as "a structure, such as a cloth, fabric or other material, that covers all, or part of" "the struts and members" and "the

[10] Exhibit 2127 is the court's claim construction order in a related lawsuit: *Aortic Innovations LLC v. Edwards Lifesciences Corp.*, No. 1:21-cv-01377-JPM (D. Del.). This is a different lawsuit than identified above (*supra* Section II(B)) involving additional related patents that were also previously challenged before the Board. *See, e.g.*, Ex. 1121, 1–4 (denying institution of IPR on U.S. Patent No. 11,129,735, and listing this other lawsuit).

open spaces, or interstices, in the spaces between those struts and members." Ex. 2124 ("0556 FWD"), 29–30; Ex. 1120 ("0034 FWD"), 40.

No further interpretation of the terms "frame" or "fibers" is needed at this time. We apply the plain meaning of those terms. Ex. 2127, 7, 22.

The Board's prior interpretation of "outer graft covering," even if we maintain it, does not squarely address the controversy here. *See, e.g.*, Ex. 2124, 29–30. That is so because the relevant limitation of claim 9 of the '834 patent is different from the language of the challenged claims in the other proceedings; claim 9 in this proceeding requires the valve is "free of a ***non-porous*** graft covering" between the first and second fibers and the frame. Ex. 1001, 22:9–12 (emphasis added). By contrast, the corresponding claim language at issue in, for example, IPR2022-00034, required the valve be "free of an outer graft covering between the fibers and the outer frame." Ex. 1120, 11; *see also* Ex. 2124, 9–10 ("valve assembly is free of an outer graft covering between the first portion of fibers and the outer frame"). For claim 9 here, Petitioner argues that valves with "porous" graft coverings are not excluded from the claim. *See, e.g.*, Pet. 60–61 (citing Ex. 1003 ¶ 189 (testifying that, if Spenser II's "porous" compressible material was added to Levi or Spenser, "there would be no '***non-porous*** graft covering'" between the fibers and the frame, and the claim limitation would be met)). We discuss this issue and any further interpretation of "non-porous" below when addressing the mapping of the prior art to claim 9.

Based on the parties' arguments, it is also evident that the parties dispute the meaning of the term "spacing" recited in claim 2 (and, similarly, in claims 17 and 18) as well as the application of such claim language to the prior art. Neither party, however, provides a proposed claim construction for those limitations including the term that is sufficiently clear and

supportable on this record that would allow us to conduct the necessary comparison of the prior art and claims. *See, e.g.*, *BlackBerry Corp. v. MobileMedia Ideas, LLC*, IPR2013-00036, Paper 65 at 19–20 (PTAB Mar. 7, 2014) ("Without ascertaining the proper claim scope, we cannot conduct a necessary factual inquiry for determining obviousness—ascertaining differences between the claimed subject matter and the prior art."). To our knowledge, neither the Board nor any court has interpreted the "spacing" limitations in any related proceeding. It is, in any event, Petitioner's threshold obligation to explain "[h]ow the challenged claim is to be construed" and "[h]ow the construed claim is unpatentable" under the grounds advanced. 37 C.F.R. § 42.104(b)(3)–(4). We discuss the "spacing" limitations in more detail in Section III(E) below.

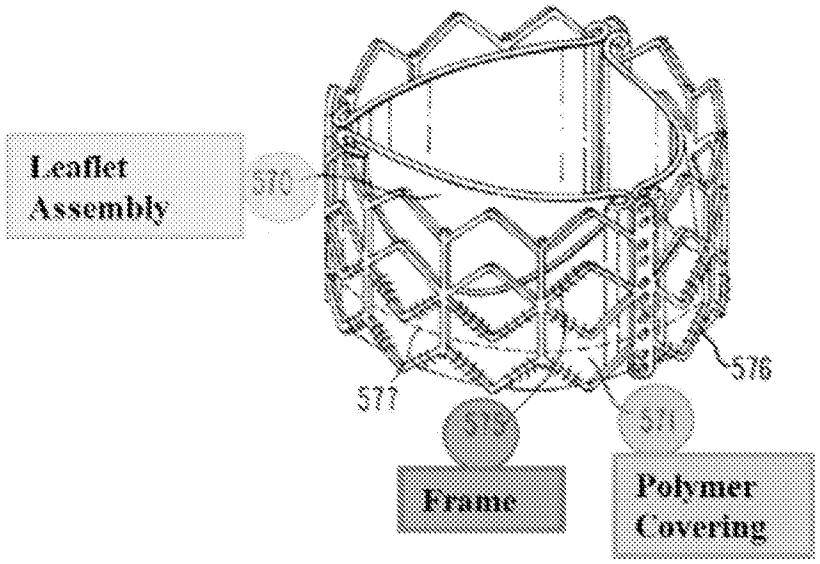
D. Asserted References

Assuming, as Petitioner does, a critical date of November 7, 2012, for the '834 patent, each of the references below is prior art. Pet. 20. Patent Owner does not contest the prior-art status of these references.

1. Spenser (Ex. 1010)

Spenser is a U.S. patent titled "Implantable Prosthetic Valve" that issued on March 31, 2009. Ex. 1010, codes (10), (12), (45), (54). Spenser therefore qualifies as prior art under pre-AIA 35 U.S.C. § 102(b).

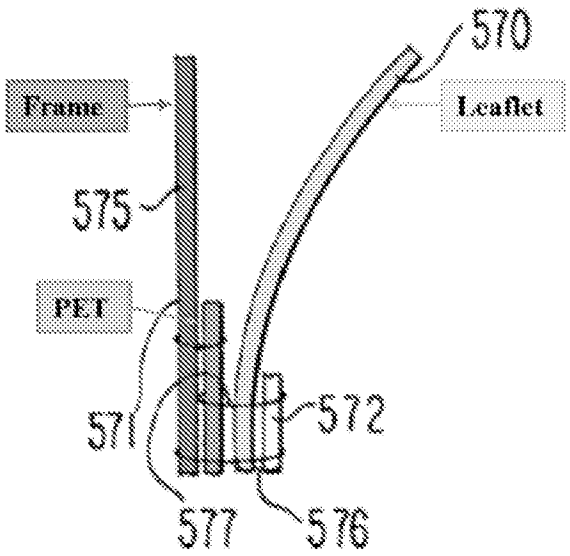
Spenser relates to a prosthetic valve for cardiac implantation. *Id.* at 1:13–15. Figure 44a of Spenser (with Petitioner's annotations) is reproduced below.



Pet. 22 (reproducing Fig. 44a of Spenser (Ex. 1010) with Petitioner's additional labeling and color-coding). Spenser's Figure 44a shows a perspective view of an implantable valve with three pericardial leaflets 570 (labeled "Leaflet Assembly" and colored yellow), located within a gridded circular frame 575 (labeled "Frame" and colored red). *Id.* at 26:30–37. As shown, Figure 44a also includes a polyethylene terephthalate (PET) layer 571 (labeled "Polymer Covering" and colored blue) that connects the leaflets to the frame. *Id.* at 26:30–42.

Spenser's Figure 44b (with Petitioner's annotations) is also reproduced below.

FIG. 44b



Pet. 29 (reproducing Fig. 44b of Ex. 1010 with Petitioner's labeling and maintained color-coding). Figure 44b (as annotated) shows a partial cross-sectional view of the valve assembly including the connections between the frame 575 (red), PET layers 571 and 572 (blue and white) and leaflet 570 (yellow). Ex. 1010, 11:36–40. Spenser discloses:

> PET 571 and 572 are used for connecting pericardial leaflets 570 to frame 575, while they are assembled in between the leaflets and the frame. A suture 577 connects pericardium leaflet 570 in between two layers of PET, while the inner layer of PET 572 is short and the outer layer is longer. Bottom attachment suture 576, connects the three layers, the leaflet and both PET layers to the frame and forms a strong sealing line. An upper suture 578 connects the outer PET layer 571 to frame 575.

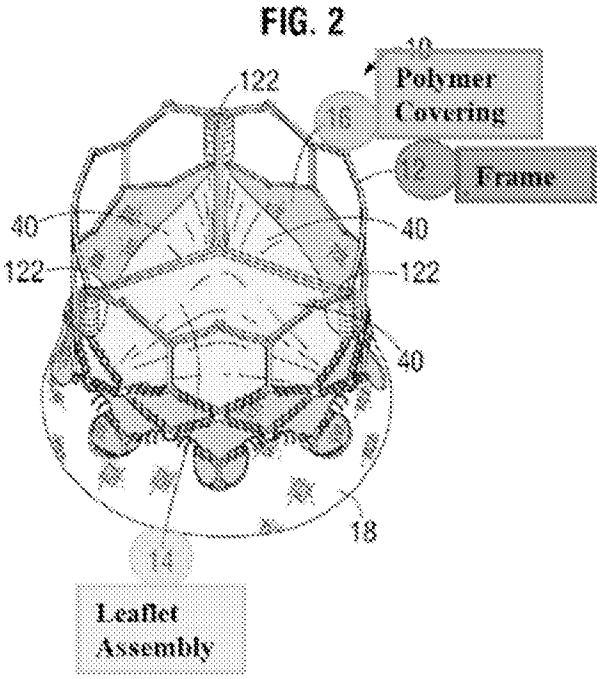
Id. at 26:40–48.

2. Levi (Ex. 1008)

Levi is a U.S. patent titled "Prosthetic Heart Valve" that issued on July 19, 2016, from an application filed on October 5, 2011. Ex. 1008,

codes (10), (22), (45), (54). Levi, thus, qualifies as prior art under pre-AIA 35 U.S.C. § 102(e).

Levi is directed to an expandable prosthetic heart valve. Ex. 1008, Abstr., 1:16–18. Figure 2 of Levi is reproduced below (as annotated by Petitioner in a similar fashion to the figures of Spenser, above).



Pet. 22 (reproducing Fig. 2 of Levi (Ex. 1008) with Petitioner's additional labeling and color-coding). Figure 2 of Levi, as annotated above, is a perspective view of an exemplary heart valve 10 including valvular structure 14 (labeled "Leaflet Assembly" and colored yellow) within a circular stent or frame 12 (labeled "Frame" and colored red). Ex. 1008, Fig. 2, 4:57–58, 5:52–58. As shown, the valve also includes inner skirt 16 (labeled "Polymer Covering" and colored blue) and outer skirt 18. *Id.* at 5:56–58. According to Levi, "[t]he illustrated valve is adapted to be implanted in the native aortic annulus." *Id.* at 5:53–56.

3. Spenser II (Ex. 1011)

Spenser II is a PCT publication titled "Paravalvular Leak Detection, Sealing and Prevention" that published on January 12, 2006. Ex. 1011, codes (10), (43), (54). Spenser II, therefore, qualifies as prior art under pre-AIA 35 U.S.C. § 102(b).

Spenser II is directed to "the prevention, detection, and repair of paravalvular leaks around cardiac valve prostheses." Ex. 1011 ¶ 1. Spenser II teaches that prosthetic valves may be implanted "either through open heart surgery or by use of newer percutaneous methods," but "[w]ith both methods paravalvular leaks are a known side effect." *Id.* ¶ 11. Spenser II notes that "[p]ercutaneous introduction of medical devices is a preferred surgical procedure" that is "safer and less invasive." *Id.* ¶ 12.

Figure 22 of Spenser II is reproduced below.

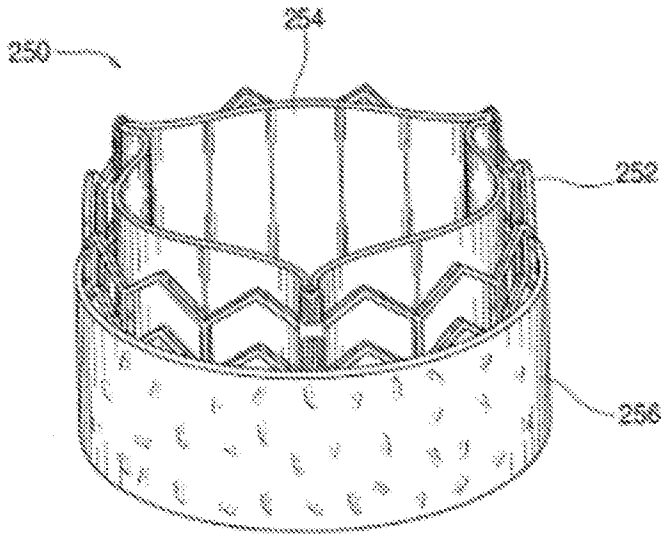


FIG. 22

Id. at Fig. 22. Figure 22 of Spenser II, shown above, is a perspective view of a preferred embodiment of the Spenser II prosthetic valve. *Id.* ¶ 85. More specifically, Spenser II's Figure 22 shows an embodiment including a layer of compressible material, such as a cloth material, along an exterior surface

of a stented valve. *Id.* The stented valve 250 includes a circular stent structure 252 surrounding a valvular structure 254. *Id.* at Fig. 22, ¶ 144. "[S]tent structure 252 is preferably made of a deformable material, such as stainless steel, adapted for radial expansion using a balloon catheter. The valvular structure 254 forms three leaflets and is illustrated in the open configuration." *Id.* ¶ 144. The device further includes circular layer of compressible material 256 surrounding the outside of stent structure 252. *Id.* at Fig. 22, ¶ 145. "The material may extend partially around the stent structure or may extend entirely around the stent structure, such as in the form of a sleeve." *Id.* "[T]he compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material." *Id.*

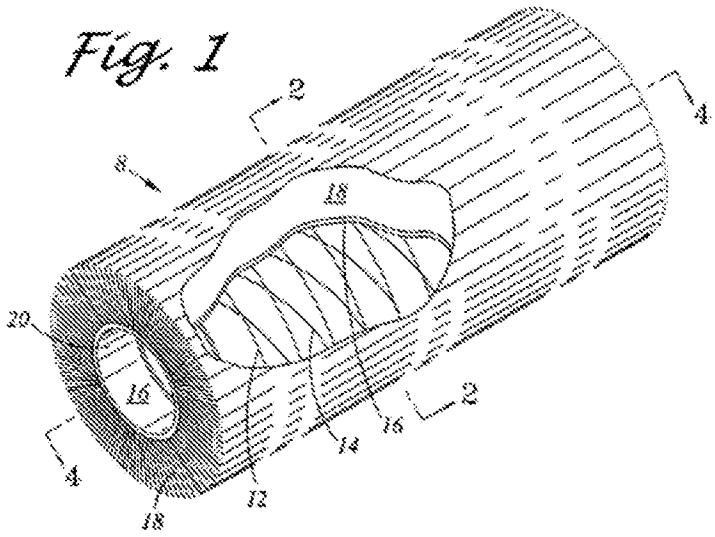
Spenser II discloses that the "compressible material expands after deployment at a treatment site" and "fills the gaps between the stented valve and the surrounding tissue," which "creates a mechanical seal that prevents paravalvular leakage." *Id.* "In one preferred embodiment, the compressible material is formed of polyethylene terephthalate (PET) and has a thickness ranging from about 1 to 5 mm." *Id.*

4. Chuter (Ex. 1116)

Chuter is a published U.S. patent application titled "Large Vessel Stents and Occluders." Ex. 1116, code (54). Chuter published October 17, 2002, and is prior art under pre-AIA 35 U.S.C. § 102(b). *Id.* at code (43).

Chuter discloses "[a]n endovascular stent for vascular vessels which can be used to occlude the vessel or which can be used to bridge damaged areas in the vessel." *Id.* at Abstr.

Chuter describes a "graft" embodiment, such as shown in Figures 1–3 of Chuter. *Id.* ¶¶ 28–30, Figs. 1–3. Chuter's Figure 1 is reproduced below.



Id. at Fig. 1. Figure 1, depicted above, is a perspective view of Chuter's graft 8, comprising a stent 12 frame formed from wires 14, which frame supports a fabric pile backing 16. *Id.* ¶ 54. Chuter teaches that, "[e]xtending circumferentially outwardly from the backing 16 is a fabric pile 18 made up of individual fibers 19." *Id.* Also, "[t]he graft has a longitudinal lumen or bore 20 extending its length to permit blood to flow." *Id.*

Figures 2 and 3 of Chuter, providing different views of the graft embodiment of Figure 1, are reproduced side-by-side below.

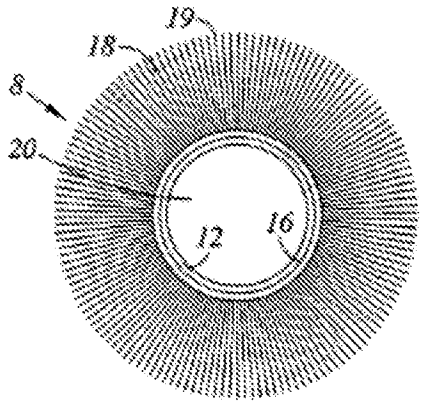


Fig. 2

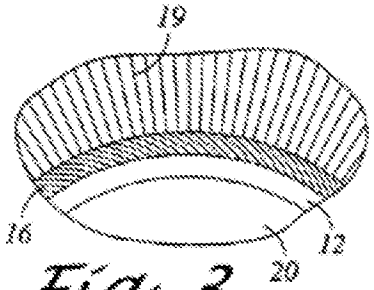


Fig. 3

Id. at Figs. 2 and 3. Figure 2 above is a cross-sectional view, and Figure 3 is an enlarged sectional view of the graft 8, showing stent 12 and fiber pile

backing 16 surrounding lumen 20. *Id.* ¶ 54. The figures also show fabric pile 18 comprising individual fibers 19 extending outwardly from the fiber pile backing 16. *Id.*

Chuter also describes several "occluder" embodiments. *See, e.g.*, *id.* at Figs. 4–12, ¶¶ 54–57. An example "occluder" embodiment is shown in Figure 8 of Chuter, reproduced below.

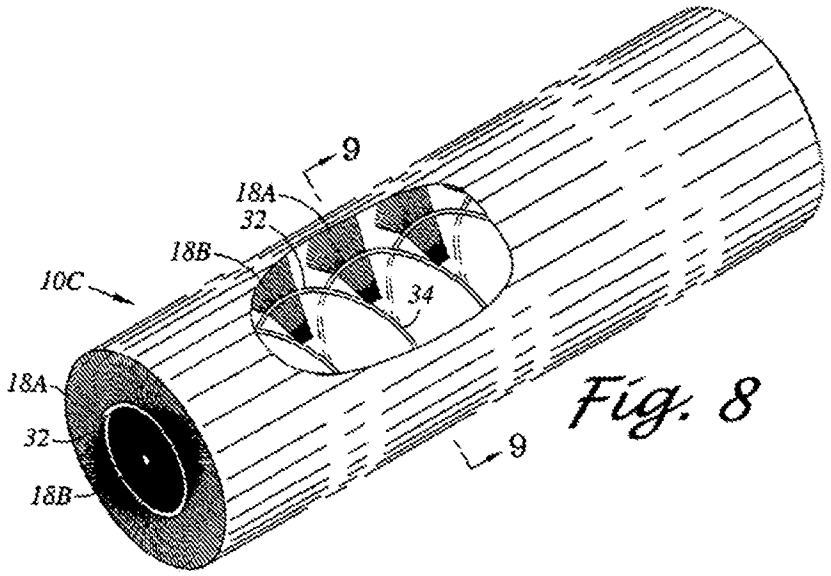


Fig. 8

Id. at Fig. 8. Figure 8 above is a perspective view of an "occluder." *Id.* ¶ 35. Chuter teaches that this embodiment includes occluder 10C comprising a stent 32 made from a helical wire frame that includes wire strand 34. *Id.* ¶ 57. In the depicted embodiment, "the wire strand has fabric threads 28 extending both outwardly and inwardly circumferentially of the stent . . . to form fabric piles extending outwardly from the occluder and inwardly of the stent to form a fabric pile 'plug.'" *Id.* As shown, fibers 18A are outwardly extending fibers, and 18B comprise inwardly extending fibers. *Id.* at Figs. 9, 12 (showing end and cross-sectional views of an occluder like represented in Fig. 8).

Chuter's Figures 9 and 10 are reproduced below.

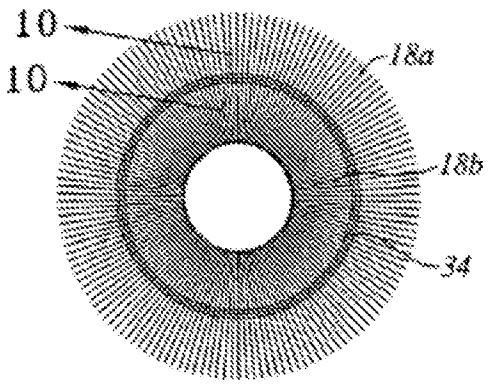


Fig. 9

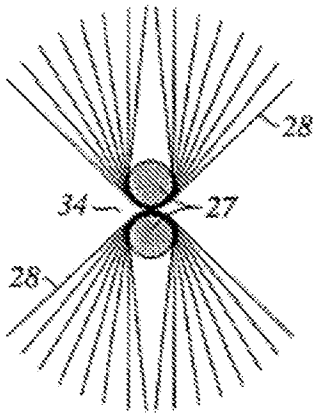


Fig. 10

Id. at Figs. 9, 10. Figure 9, shown above, is an end view of the occluder of Figure 8 and shows fibers 18a and 18b extending outwardly and inwardly from wire strand 34. *Id.* ¶ 57. Figure 10 is an enlarged cross-sectional view along lines 10-10 of Figure 9, depicting wire strand 34, comprised of at least two twisted wires 27 such that fabric threads 28 extend from those wires. *Id.* ¶¶ 56–57; *see also id.* at Figs. 5, 6, 7 (depicting an occluder comprising at least one helically wound double wire strand 26 similar to the wire strands 27 of Fig. 10). Chuter teaches that the fibers are made of biocompatible materials such as polyester. *Id.* ¶ 22.

E. Spenser II Combinations (Grounds 1 and 2)

Petitioner argues that claims 2, 9, 17, and 18 would have been obvious over either Spenser or Levi, in further combination with Spenser II. Pet. 22–76; *see id.* at 48–51 (claim 2), 60–61 (claim 9), 72–76 (claims 17 and 18). Patent Owner opposes that argument. Prelim. Resp. 3–27 (counterargument for claims 2, 17, and 18), 27–33 (counterargument for claim 9).

1. Claims 2, 17, and 18

a) Petitioner's Argument

Although the dispute at this stage concerns whether the combined art discloses the "spacing" limitations in claims 2, 17, and 18, we summarize Petitioner's contentions about other limitations and the asserted motivations for combining the art's teachings for context before returning to the "spacing" limitations.

Petitioner argues that Spenser or Levi discloses all the limitations in claim 1 except for those related to first and second fibers. Petitioner argues that Spenser, for example, teaches claim 1's preamble language (if it is limiting), the limitations about a "frame" that is "radially expandable," a "leaflet assembly," a "polymer covering," and that the claimed valve may be "endovascularly deployed." Pet. 24–30, 35 (citing, e.g., Ex. 1010, Figs. 44a–44c; Ex. 1003 ¶¶ 97–114, 126–140); *see also id.* at 72–73, 75–76 (similar argument for analogous limitations in claims 17 and 18).

Claim 1 further requires, *inter alia*, "a first plurality of fibers that extend away from the frame," and "a second plurality of fibers that is positioned radially inwardly from the first plurality of fibers," which second plurality of fibers are "in direct contact with the frame." *See supra* Section II(D).[11] For those limitations, Petitioner turns to Spenser II. Pet. 30–34 (first plurality of fibers), 44–48 (second plurality of fibers). Petitioner contends that Spenser II's "compressible material 256" (*see supra* Section III(D)(3)) meets the various "fibers" limitations. *Id.* More

[11] Claims 17 and 18 are similar with respect to the "fibers" limitations, but claim 18 recites "a plurality of fibers that extend away from the frame," without specifying "first" and "second" pluralities like claims 1 and 17. Ex. 1001, 22:38–24:18.

specifically, Petitioner cites Spenser II's teaching that the compressible material "may resemble a cloth or fabric having small fibers extending from the surface," and Petitioner contends these fibers extending from the surface are the "first plurality of fibers." Pet. 31 (citing Ex. 1011 ¶ 145, Fig. 22; Ex. 1003 ¶ 117). For the second plurality of fibers, Petitioner contends "the Board has previously found Spenser II's compressible material includes a cloth/fabric of fibers, forming a 'graft covering,' that is radially inward from the outwardly extending fibers," and Petitioner argues "[t]his inner cloth/fabric layer is the 'second plurality of fibers,'" as claimed. *Id.* at 45–46 (citing Ex. 1120 (0034 FWD), 46–49; Ex. 1003 ¶¶ 150–152), 47–48 ("In one embodiment, Spenser II's compressible material includes a base layer of fibers 'forming a mesh' and a plurality of fibers extending radially outwardly 'that end therefrom and into engagement with native leaflets.") (quoting Ex. 1003 ¶ 151; citing Ex. 1074 (Norris) as illustrating another known sealing fabric for, e.g., endovascular grafts with a ground layer and having fiber loops extending outwardly from the ground layer).

Petitioner argues that a POSA would have been motivated to add Spenser II's compressible material to Spenser's valves, or to have substituted Levi's outer skirt with Spenser II's compressible material, for the purposes of preventing paravalvular leakage (PVL). Pet. 23–24, 31–34. Petitioner contends that its asserted motivation here is consistent with the Board's findings on the motivation issue in related proceedings and, for the Levi and Spenser II combination, involves swapping interchangeable features that serve similar purposes. *Id.* at 31–34 (citing, e.g., Ex. 1117, 64; Ex. 1003 ¶¶ 119–125).

For the "spacing" limitations as recited in claim 2 (as well as claims 17 and 18), Petitioner contends those limitations are obvious over

Spenser II. Pet. 48–51. Petitioner contends a POSA "would have understood" that Spenser II's "base layer (e.g., second plurality of fibers) would define spacings extending through a thickness of fibers created by a distance between adjacent fibers." *Id.* (citing Ex. 1003 ¶¶ 158–167). According to Petitioner, because Spenser II teaches that its material is "compressible" it must have spaces between fibers and such "spaces would need to exist in the fibrous *and* base layers." *Id.* at 49. Moreover, Petitioner contends, because Spenser discloses that its compressible material can expand and encourage coagulation, spaces must exist to permit this expansion and coagulation. *Id.* at 49–50 (arguing that "in a porous material, such as Spenser II's compressible material, spacings would necessarily exist" and extend to the frame because the material "presses against the frame") (citing Ex. 1123 (Infringement Contentions), 78–80). And lastly, Petitioner contends that the '834 patent provides no detail about how to arrange the fibers to provide the "spacing" claimed. *Id.* at 51.

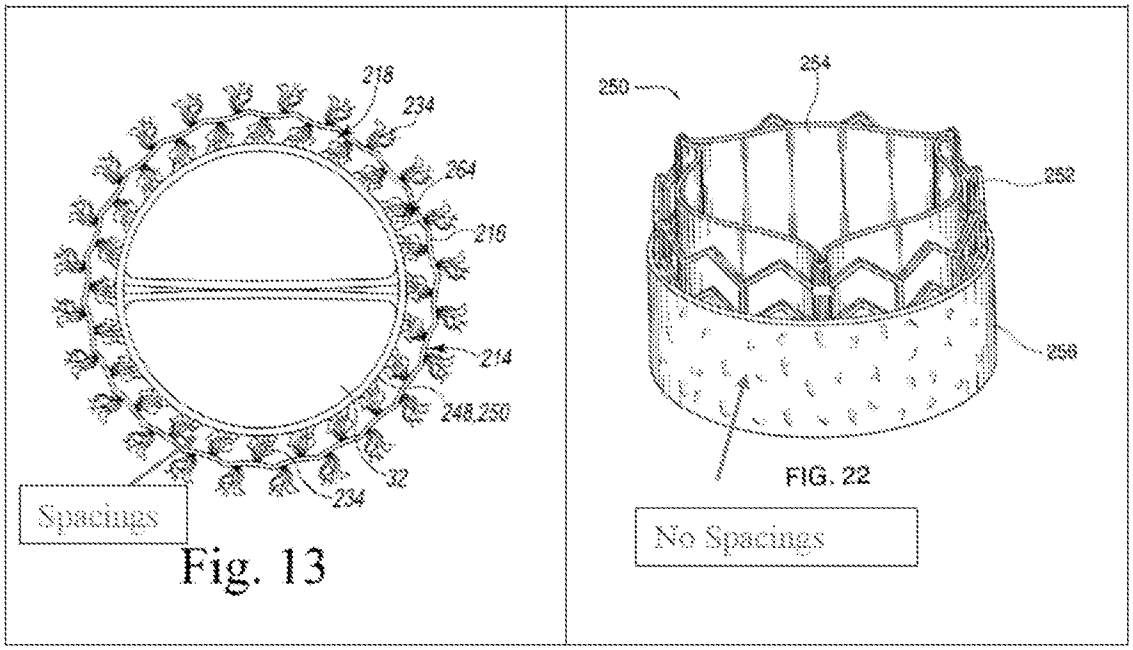
b) Patent Owner's Argument

Patent Owner argues that Spenser II does not teach or render obvious the "spacing" limitations of the claims. Prelim. Resp. 4–27; Paper 11, 1–5.

Patent Owner contends the claimed "spacing" limitations are different from what is disclosed in Spenser II and other asserted art. Prelim. Resp. 4–9. According to Patent Owner, the "spacing" limitations "allow for a valve with a narrow crimp profile that also seals against paravalvular leakage" upon expansion of the frame. *Id.* at 4–5 (citing, e.g., Ex. 1001, Figs. 13, 14; Ex. 2002 ¶ 36). In support, Dr. Brecker testifies that the claimed spacings "permit a delivery profile low enough for transfemoral delivery and formation of a paravalvular seal by compression of the fibers atop or within the spacings after the valve is expanded inside the body." Ex. 2002 ¶ 36. In

related proceedings, Patent Owner argues, the Board credited Dr. Brecker's testimony that "a sparse distribution of fibers with significant gaps and spaces would be porous, at least until compressed within the body." Prelim. Resp. 5–6 (citing, e.g., Ex. 2124 (0556 FWD), 33–34 (quoting Ex. 2103 ¶ 160)). Moreover, Patent Owner contends, both parties' experts agree that they had never seen a distribution of fibers in a prior art valve or stent graft like shown in the '834 patent outside of the patent itself. *Id.* (citing Ex. 2052 (Buller deposition), 167:10–15, 169:5–25; Ex. 2002 ¶ 38).

Patent Owner also contends that Spenser II was distinguished, and indeed Spenser II's cited subject matter disclaimed, during prosecution. Prelim. Resp. 6–12. According to Patent Owner, "Spenser II, and its compressible material in particular, was expressly distinguished in prosecution as lacking the claimed 'spacings.'" *Id.* at 7–9 (citing Ex. 1002, 1001–1002 (prosecution argument asserting a distinction with the claimed "spacings" compared to Spenser II's compressible material as in Fig. 22)); *see supra* Section II(E). Patent Owner argues the distinction between the claimed spacings and Spenser II's disclosure is apparent, as seen in the image below:



Prelim. Resp. 10. The image above shows Figure 13 of the '834 patent (on the left) side-by-side with Spenser II's Figure 22 (on the right), with Patent Owner's annotations indicating "Spacings" on Figure 13 and "No Spacings" on Figure 22. *Id.* And, after applicant argued during prosecution that the claimed "spacing" was absent in Spenser II (and other prior art), Patent Owner emphasizes that the Examiner allowed the claims and remarked that "[t]he prior art does not disclose or render obvious the prosthetic heart valve defining a spacing extending through a thickness of the plurality of fibers." *Id.* at 7 (quoting Ex. 1002, 850).

Patent Owner argues that, even if the Board were to conclude that Spenser II's compressible material was not dispositively distinguished or disclaimed in prosecution, Petitioner has not shown that Spenser II teaches the "spacing" limitations of the claims. Prelim. Resp. 16–27.

Patent Owner contends that Petitioner is invoking an inherency theory because Spenser II is plainly silent about any "spacing" that might meet the claim limitations. *Id.* at 17–22 (citing Petitioner's argument about a POSA

understanding a "spacing" must necessarily be present). And, according to Patent Owner, Petitioner's inherency theory is flawed. *Id.* Dr. Brecker testifies, for example, that Spenser II "depicts a thick, opaque, seal without any spacings within the base layer . . . [and] we cannot assume that any imagined 'spacings' would also 'extend' to the frame or through the cells of the frame" like claimed. Ex. 2002 ¶¶ 50–52 (citing, e.g., the Board's finding in related matters characterizing Spenser II's compressible material as a graft covering similar to a "***densely woven*** outer PET skirt"). Patent Owner contends that Petitioner's theory, including the notion that Spenser II's compressible material must be "porous," is inconsistent with Dr. Buller's prior testimony, which characterized Spenser II's material as "sufficiently dense" and fluid impermeable. Prelim. Resp. 19 (citing Ex. 2128 ¶ 222). Moreover, Patent Owner contends, if the claimed spacings were "necessarily" present, one would expect to see such spacings in real-world embodiments of Spenser II, like the Walther valves. *Id.* at 20–22. But, according to Patent Owner, Petitioner's declarant admits that no such spacing is visible in the Walther (or similar) valves. *Id.* (citing Ex. 1128, 70:22–71:5; Ex. 2052, 200:11–14); Ex. 2002 ¶ 54 (testifying no opening or spacing like claimed is present in the Walther valve).

And, for a host of reasons, Patent Owner argues that Petitioner's assertion that Spenser's compressible material "must have spaces" in order to compress, expand to fill gaps, and coagulate blood is wanting for support and, therefore, fails. Prelim. Resp. 22–27 (quoting Pet. 47–50). For example, Patent Owner notes that Petitioner's "real-world products" embodying the Spenser II design, like Walther, are described as being compressible, promoting tissue ingrowth, filling gaps, and clotting blood. *Id.* at 22–23 (citing Ex. 1007, 1, 7). Yet, according to Patent Owner and as

discussed above, such products do not reveal any "spacing" that extends through a base layer to the frame or the cells like claimed. *Id.* (citing Ex. 2002 ¶ 56); *see also* Ex. 2002 ¶¶ 56–59 (testifying that, based on Spenser II's disclosure, it is evident the fibers extending from the surface of the compressible material address the goals of filling gaps between the valve and surrounding tissue, coagulating blood, etc., without demonstrating any "spacing" that extends to the frame like claimed); Ex. 1011 ¶ 145.

c) Analysis

On this record, we cannot agree with Petitioner's position. The lack of a coherent, adequately supported claim construction for the "spacing" limitations on this record prevents the Board from determining whether claims 2, 17, and 18 would have been obvious over Spenser or Levi, in further combination with Spenser II. It is Petitioner's threshold obligation to explain how the claims are to be construed. 37 C.F.R. §§ 42.104(b)(3)–(4). But, as we explain below, based on the parties' arguments and evidence presented here, we are unable to construe the claimed "spacing" language at the level of detail necessary to resolve the issues in dispute. *See Microsoft Corp. v. Uniloc 2017 LLC*, IPR2019-01125, Paper 8 at 16–17 (PTAB Nov. 27, 2019) (denying institution where the Board could not determine "the scope of the claims . . . without undue speculation . . . [and, thus,] the differences between the claimed invention and the prior art cannot be ascertained"). We, thus, conclude that Petitioner has not met its burden to show that it is reasonably likely to prevail on the Spenser II-based challenge to claims 2, 17, and 18 (Grounds 1 and 2).

Petitioner argues that no claim construction is needed while simultaneously asserting that the claims should be interpreted in view of Patent Owner's infringement allegations in the related litigation. Pet. 21

(citing the complaint (Ex. 1122) and infringement contentions (Ex. 1123)); Paper 9, 1 (image of "Prior Art (Walther and Spenser II)" next to image of "Accused Product (SAPIEN 3 Ultra)").

This path is ultimately not helpful in clarifying the meaning of the claimed "spacing" such that we might sufficiently address the merits of Petitioner's challenge. Implicit in Petitioner's position is that the claims cannot encompass the cloth design used with the accused SAPIEN 3 Ultra valve without also encompassing Spenser II's compressible "cloth" material. Ex. 1011 ¶ 145 (describing Spenser II's compressible material as "resembl[ing] a cloth or fabric having small fibers extending from the surface"); Paper 9, 2 ("PO never explains why the spacings in the prior art cloths are outside the claims but the spacings in the SAPIEN 3 Ultra cloth are covered.").[12] We see no adequate basis on this record to conclude that, if the SAPIEN 3 Ultra design includes "spacing" as claimed, such "spacing" must likewise be found in Spenser II's teachings.

Details about SAPIEN 3 Ultra's engineering are not identified or explained here and, even looking at Petitioner's cited photos, it is not evident that the "fibrous cloth" of SAPIEN 3 Ultra is substantially the same

[12] Petitioner contends we should apply the "plain and ordinary meaning" of spacings as "the only affirmative definition offered in this IPR." Paper 9, 2. But, insofar as Petitioner contends such a meaning covers any and all cloth/fabric grafts, sleeves, etc., it is not evident that such a construction is defensible. Indeed, as we discuss in this section, during prosecution the applicant identified at least some types of fibrous cloth materials as not including the spacing as claimed. *See supra* Section II(E). That Patent Owner may have styled its interpretation of the "spacing" limitations in litigation as based on a "plain and ordinary meaning" does not reveal an admission on Patent Owner's part that all cloths/fabrics are within that claim scope. Ex. 1147, 44; Paper 11, 3 (arguing against any such admission).

as the Spenser II or the Walther design. Paper 9, 2; Ex. 2052, 104:17–105:7 (Dr. Buller testifying that Walther is a "real-world embodiment" of Spenser II's Fig. 22). Indeed, the available (yet limited) evidence suggests there may be important differences in those designs. *Compare* Ex. 1128, 132:14–133:10 (Buller testimony about an image of the SAPIEN 3 Ultra, describing as "clearly a loose fabric, and there are clearly holes between the fibers . . . going all the way through it"),[13] *with id.* at 70:22–71:5 (Buller testimony about the Walther valve that "I certainly can't see fibers, and I can't see individual things that I can say are openings").

We are also unpersuaded that the claimed "spacing" should be interpreted to read on all fibrous cloths attached to a frame. *See* Paper 9, 5 (asserting all fibrous cloths have "spacings"). The prosecution history suggests the contrary. As discussed above, applicant contrasted the claimed "spacing" with the prior art's "very tightly knitted outer seal made of tightly knitted fibers" and expressly cited Spenser II's Figure 22 and Walther (Ex. 1007) as examples of designs with a "lack of 'spacings'" between the fibers like the claimed "spacing." Ex. 1002, 1001; *see also id.* (suggesting the claimed "spacing" design is distinct in its more "loosely defined fiber structure"). Petitioner's expert in related litigation also testified that "there does not appear to be any dispute that [the '834 patent] do[es] not include cloths like those described in Walther and Spenser II." Ex. 2141 ¶¶ 33–35. We acknowledge, as Petitioner argues, that all fibrous cloths would, in some

[13] We note, however, that, in further questioning, Dr. Buller raised issues with the provenance or quality of the images. Ex. 1128, 133:12–21; *see also id.* at 71:2–72:4. Our discussion here should in no way be read as indicating that the SAPIEN 3 Ultra valve is, in fact, covered by the claims. Also, this cited testimony underscores the apparent difficulty in determining whether certain design features are present in these devices from photos alone.

absolute sense, have spaces between fibers. Paper 9, 5 (citing Ex. 1146, 185:18–20).[14] But construing the "spacing" limitation to encompass all such cloths would, at least on this record, appear to erase the distinction (or potential disclaimer) that applicant made during prosecution over cloths comprising "tightly knitted fibers" such as allegedly exemplified in Spenser II. We are not, thus, persuaded that such a broader construction is correct.

In additional authorized pre-institution briefing, Petitioner also argues that, if any prosecution disclaimer occurred, it is "much broader than just Spenser II" and "includes materials like the cloth on Petitioner's accused SAPIEN 3 Ultra valve." Paper 9, 4 (describing the accused valve as having "tightly knitted fibers"). We agree with Petitioner that any disclaimer, assuming applicant's representations rise to that level, was not limited to Spenser II. Spenser II was cited as an example of cloths of "tightly knitted fibers" that purport to fall outside the scope of the claimed "spacing." Ex. 1002, 1001. It does not, however, necessarily follow that such "disclaimer" would extend to all cloths, including SAPIEN 3 Ultra's cloth feature. Paper 11, 3 ("[A] statement about Spenser II's compressible material is not a statement about '***all*** sleeves, layers, and cloths.'"). As explained above, we lack sufficient detailed technical information about the

[14] As Patent Owner points out (Paper 11, 5), although Dr. Brecker testified that "[a]ny piece of fabric would have spaces between the fibers however it was produced," he continued noting: "That's not what I'm talking about and that's not what the patentee is talking about." Ex. 1146, 185:14–186:6 (distinguishing spaces that would exist, e.g., if reduced to the molecular level or by inherency). We are not persuaded by Petitioner's argument that Patent Owner (or Dr. Brecker) are proposing conflicting claim constructions in this IPR versus what is proposed before the district court. Paper 9, 3.

SAPIEN 3 Ultra device and, thus, have no adequate factual basis on which to accept Petitioner's argument that this device includes "tightly knitted fibers" of the sort distinguished in prosecution. Moreover, applicant expressly identified the SAPIEN 3 Ultra valve during prosecution and suggested it was "covered by the claimed invention." Ex. 1002, 1152–1153 (describing the SAPIEN 3 Ultra as including fibers in a "mesh" pattern with "openings" as then recited in the claims). Given this prosecution history and the limited record here, we cannot agree that there was any disclaimer that clearly and unambiguously extends to the SAPIEN 3 Ultra valve.

Petitioner also argues that applicant mischaracterized Spenser II during prosecution. Pet. 18, 99. According to Petitioner, Spenser II never describes its compressible material as including "tightly knitted fibers" and a POSA would, instead, have understood Spenser II's compressible material as comprising "loose, porous materials." Pet. 18, 99. We agree with Petitioner that the phrases "tightly knitted" and "tightly knitted fibers" do not appear in Spenser II. At the same time, neither does Spenser II describe its compressible material as being "loose" and "porous." Notably, in prior proceedings before the Board, Petitioner's declarant Dr. Buller testified that Spenser II's compressible material "includes a plurality of PET fibers on the inward-facing surface of the compressible material" (i.e., the "base layer" and alleged "second plurality" of fibers here; Paper 9, 5), that is "sufficiently dense to prevent blood from leaking through the cloth/fabric." Ex. 2128 ¶ 222; *see also* Ex. 2122, 20:2–22:18 (testifying that "nonporous" as used in the Specification means "that fluid would not pass through it" and such fluid includes "all components of blood"). We find that Dr. Buller's description of Spenser II as having a dense, blood impermeable base layer is, on balance, more consistent with applicant's characterization of Spenser II as

having an arrangement of "tightly-knitted fibers"—even if some imagined or microscopic spaces between fibers might still exist in a base layer. Ex. 2128 ¶ 222; *see also* Ex. 2002 (Brecker testimony) ¶¶ 42–45 (testifying, *inter alia*, that the description of a "tight fitted outer seal is . . . consistent with Spenser II's Figure 22" and "knitted" is consistent with Buller's testimony describing Spenser II's compressible material as "velour-like woven or knitted" PET (citing Ex. 1003 ¶ 162; Ex. 2134 ¶ 56). We are, thus, unpersuaded on this record that applicant mischaracterized Spenser II.

Altogether, the parties' alleged "plain meaning" yet otherwise undefined interpretation of the "spacing" limitations leaves the Board with insufficient clarity about what the claimed "spacing" means in the affirmative. Paper 9, 3 (arguing "plain meaning"); Paper 11, 3 (arguing applicant's arguments are in "full harmony with the plain meaning"). The intrinsic evidence is minimally helpful: the Specification does not use the term "spacing" in relation to the positioning of adjacent fibers; the drawings might be helpful but neither party proposes a specific construction that is reliant on them.[15] The prosecution history provides clues, but portions of the prosecution record are arguably confounding. The applicant distinguished

[15] For example, Dr. Brecker, in support of Patent Owner's argument, identifies several of the patent drawings and testifies that, "as is particularly clear in Figure 13 (but also present elsewhere), ***there are gaps and spaces between the fibers that extend to the frame***" and then proceeds to testify that prior art, like Spenser II's compressible material, "bears no resemblance" to the "exemplary" spacings identified in prosecution. *See, e.g.*, Ex. 2002 ¶¶ 42–43. Dr. Brecker's articulation of a "spacing" does not seem to add anything meaningful beyond the language of the claim as written. And, simply comparing the patent drawings to the prior art drawings presumes a sort of "know-it when you see it" interpretation—it is not an affirmative construction for a "spacing" as claimed.

the claimed "spacings" from "tightly knitted fibers." Ex. 1002, 1001. At what point, however, does a cloth of "tightly knitted fibers" qualify as more "loosely defined" and come within the scope of the claimed "spacing?"[16] *Id.* The applicant also described the "spacing" in semi-functional terms based on "advantages" provided by the claim feature. *See, e.g., id.* (asserting, e.g., that the spacing permits "expansion and contraction" with "lesser rigidity"); *see also id.* at 1133, 1140 (asserting, e.g., "reduce[d] restrictions" and avoidance of "restrained valve foreshortening" with the then-claimed "openings"). It is not, however, evident where the Specification supports such "advantages"—no citations were given in prosecution. And, in prosecution of related applications, applicant argued, for example, that "[w]hile all fibers have some degree of being spaced-apart, the construction from Applicant's claimed invention clearly requires ***some level more spacing***." Ex. 1149, 13–14 (assertion differences over "Dehdashtian" (alias to Spenser II)) (emphasis added). On this record, what would suffice as "some level more spacing" is unclear. *Id.*

Petitioner contends that Patent Owner's prosecution statements provide no "objective boundaries" for the claimed "spacings" and Patent Owner "never identifies any boundaries that would enable [POSAs] to determine which spacings are within the claims." Paper 9, 4. We agree that parts of the prosecution history raise questions as noted above. Distinctions were drawn during prosecution against Spenser II's compressible material,

[16] Defining an invention with words of degree is not necessarily problematic, but can raise indefiniteness issues if the baseline is unclear to the skilled artisan. *See Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370 (Fed. Cir. 2014); *Liberty Ammunition, Inc. v. United States*, 835 F.3d 1388, 1395 (Fed. Cir. 2016).

but even that is arguably muddled by terminology (e.g., tightly knitted vs. loosely defined) that finds no explicit support in the patent or cited prior art and by vague language (e.g., "some level more spacing") used in subsequent prosecution.

We do not, however, agree that we should thus interpret the claims to cover all fabric cloths including those described in Spenser II and as used with the SAPIEN 3 Ultra under the banner of a "plain meaning" as we also already explained. We simply cannot independently discern what the claimed "spacing" means on this record, and the parties offer insufficient guidance. Whether the alleged absence of "objective boundaries" for the "spacing" limitations supports a conclusion that the claims are invalid as indefinite would be a question for the court. Paper 11, 4 (arguing that a conclusion that the claims are indefinite "is outside the Board's statutory [IPR] jurisdiction").[17]

For the above reasons, we conclude that there is a required claim element—the "spacing" limitation of claims 2 (and similarly claim 17 and 18)—without a sufficiently clear meaning on this record. We are, thus, unable to conduct the required prior-art analysis of those claims relative to Petitioner's Spenser II-based challenges (Grounds 1 and 2). Under these circumstances, Petitioner has not shown that it is reasonably likely to prevail on its Spenser II-based challenge to claims 2, 17, and 18.[18]

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[17] We express no opinion here on the legal question of indefiniteness.
[18] Because we deny Petitioner's Spenser-II based challenge for other reasons, we do not further address Patent Owner's contention that 35 U.S.C. § 325(d) should bar consideration of such challenge. Prelim Resp. 12–16.

2. Claim 9

Claim 9 depends from claim 1 and further requires "the prosthetic heart valve is free of a non-porous graft covering between the first plurality of fibers and the frame and the second plurality of fibers and the frame." *See supra* Section II(D). Petitioner contends this subject matter would have been obvious over Spenser or Levi, in further combination with Spenser II. Pet. 60–61 (arguing Spenser II's material is preferably "porous").

The dispositive issues here are twofold: First, what does "non-porous" mean as used in the phrase "free of a non-porous graft covering"; and second, whether Spenser II teaches that its compressible material is porous or non-porous.[19] We address those issues in turn.

From the intrinsic evidence of record, we conclude that "non-porous" as used in the '834 patent means "preventing passage of fluid through its substance."[20] For example, the patent describes a stent covered with

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[19] Patent Owner contends that the Board has twice decided that Petitioner has failed to prove Spenser II is "free of" a "graft covering" of any kind. Prelim. Resp. 27–29, 31–33 (arguing collateral estoppel should bar Petitioner's current argument). Whether Spenser II is free of ***any*** kind of graft covering does not resolve the present issue. The "free of" language is essentially a negative limitation. A determination that Spenser II includes any type of "graft covering" and, thus, is not "free of" such covering, as in the prior proceedings, involved a narrower limitation than involved in this case. If Spenser II included ***any*** graft covering (e.g., porous or non-porous), the limitation in the prior proceedings would not be met. But here, the limitation reciting "free of a ***non-porous*** graft covering" could be met by prior art that included a ***porous*** graft covering, as argued by Petitioner. For at least these reasons, collateral estoppel does not apply.

[20] We may also use the phrase "fluid impermeable" in this Decision, which we understand carries the same contextual meaning as "non-porous." *See* Ex. 3002, https://www.merriam-webster.com/dictionary/impermeable (defining "impermeable" as "not permitting passage (as of a fluid) through its substance").

polyester "or other nonporous material . . . that prevents fluid from passing through the outer surface." Ex. 1001, 7:30–36; *see also id.* at 8:51–57 (describing application of a "nonporous covering material" and "[i]n that way, the entire outer surface . . . is covered to prevent fluid from passing therethrough"), 9:35–38 ("As a result [of covering with polyester or other "nonporous" material], fluid is prevented from passing through the surface").

Petitioner's declarant agrees with this interpretation. Prelim. Resp. 29–30 (citing Buller testimony). When asked what "nonporous" meant in his prior declaration, Dr. Buller testified that he "used it in exactly the same sense as I believe it is used in the [related[21]] '236 patent in the specification, that fluid would not pass through it." Ex. 2122, 20:2–21:3; *see also id.* at 21:17–22:1 ("And so if fluid will not pass through it, then, in the meaning of the term [of the] '236 Patent, it is nonporous."). Dr. Buller also confirmed that fluid, in the context relevant here, includes blood and its fluid components. *Id.* at 22:2–8 (confirming "fluid" in the context of the relevant valves includes "plasma" (i.e., "blood and water")).

With this interpretation in mind, we turn to the second dispositive issue. Petitioner does not dispute that Spenser II includes a "graft covering" as the Board has previously interpreted that term. Pet. 60–61; Prelim. Resp. 28–29 (citing Ex. 2124 (0556 FWD), 38). Instead, Petitioner argues here that Spenser II's covering material is "porous" and not otherwise excluded from satisfying claim 9's "free of a non-porous graft covering" limitation.

[21] The '834 patent and '236 patent (Ex. 2133) that was challenged in a related proceeding (IPR2022-00556) share, in all relevant respects, the same specification disclosures.

Pet. 61 (citing Ex. 1003 ¶ 189 (testifying that "Spenser II's compressible material would have preferably been a porous, compressible material")).

On this preliminary record, we disagree with Petitioner's argument. Petitioner's expert, Dr. Buller, has testified that Spenser II's compressible material would be "sufficiently dense to prevent blood from leaking through the cloth/fabric." Prelim. Resp. 29 (citing Ex. 2128 ¶ 222). Dr. Brecker agrees—testifying that the POSA "would understand that the compressible material [of Spenser II] would be 'sufficiently dense' to prevent blood from leaking because that is its principal purpose." Ex. 2002 ¶¶ 71–72. As argued by Patent Owner, "nothing in [Spenser II's] Figure 22 or its description . . . suggest[s] the compressible material is 'porous'" (i.e., here, fluid permeable). Prelim. Resp. 30.

On balance, we agree with Dr. Brecker that Spenser II's disclosure related to the compressible material "indicates a 'non-porous graft covering' which [POSAs] would have favored as a solution to prevent PVL." Ex. 2002 ¶¶ 71–72 (noting that Spenser II teaches its compressible layer is preferably formed of polyester/PET and "a PET layer as depicted in Figure 22 would not be suggestive of a 'porous' covering"). Because the proposed combination of Spenser or Levi with Spenser II would involve a modified valve having a non-porous (i.e., fluid impermeable) covering material, the limitation requiring the heart valve be "free of a non-porous graft covering" is not met.

3. Conclusion

On this record, Petitioner has not shown it is reasonably likely to prevail in establishing that at least one of claims 2, 9, 17, and 18 would have been obvious over Spenser or Levi in further combination with Spenser II under asserted Grounds 1 and 2.

F. Chuter Combinations (Grounds 3–6)

Petitioner contends that claims 2, 9, 17, and 18 would have been obvious over either Spenser or Levi, in further combination with Chuter (Grounds 3 and 4). Pet. 76–97; *see id.* at 87–89 (claim 2), 91–92 (claim 9), 95–97 (claims 17 and 18). Petitioner also contends that claims 2, 9, 17, and 18 would have been obvious over either Spenser or Levi, in further combination with Chuter and Spenser II (Grounds 5 and 6). *Id.* at 97–98.[22] Petitioner's argument under Grounds 5 and 6 mirrors the argument for Grounds 3 and 4, differing only insofar as Petitioner asserts that Spenser II would have provided "additional motivation to add Chuter's fiber pile to Spenser's and Levi's valves." *Id.* (citing Ex. 1003 ¶¶ 336–337).

As we discuss below, Petitioner's challenge, as well as Patent Owner's counterargument, focus on two embodiments of Chuter relied upon in the proposed combination with either Spenser or Levi. One of those embodiments is a graft embodiment including a stent frame that is covered by a fabric pile backing layer, and with a fabric pile of individual fibers extending outwardly from the backing layer, such as shown in Figures 1–3 of Chuter. *See, e.g.*, Pet. 80, 85; Prelim. Resp. 35–36; Ex. 1116, Fig. 2; *see supra* Section III(D)(4). The second embodiment involves an "occluder," with individual fibers radiating outwardly and inwardly from the frame, such as shown in Figures 8–10 of Chuter. *See, e.g.*, Pet. 80, 86; Prelim. Resp. 57–58; Ex. 1116, Figs. 8–10.

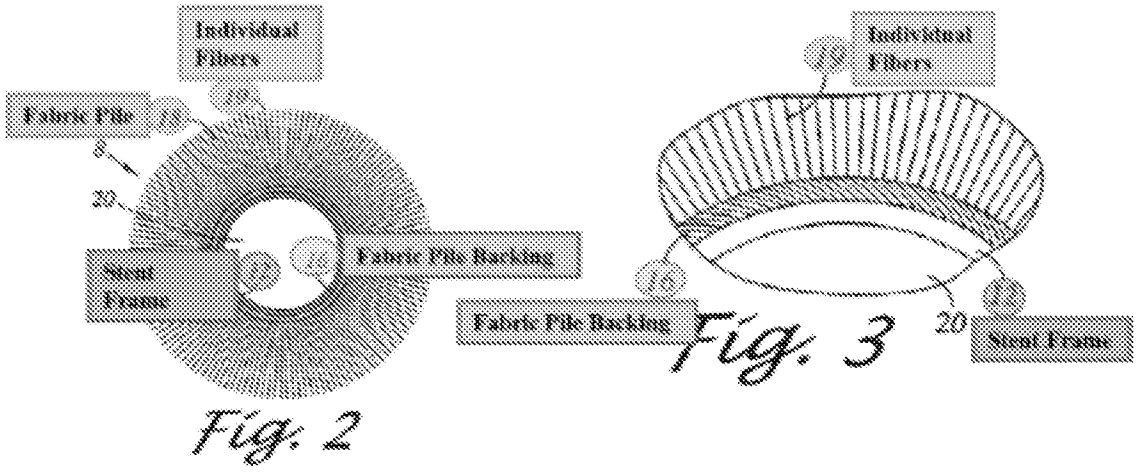
[22] The Petition uses the heading "Grounds 4–6," which appears to be a typographical error. *Compare* Pet. 97, *with* Ex. 1003, 167 (corresponding page from Dr. Buller's declaration, using the heading "Grounds 5–6").

1. Analysis

a) Chuter Graft/Backing-Layer Embodiment (all claims)

Petitioner's challenge based on the combination of Spenser or Levi along with Chuter's backing-layer embodiment resembles Petitioner's challenge based on the combination of Spenser, Levi, and Spenser II from above. Petitioner relies on Chuter in much the same way as it relied on Spenser II—citing Spenser or Levi for all the limitations except the first and second pluralities of fibers, the "spacing" limitations (of claims 2, 17, and 18), and the "free of a non-porous graft covering" limitation (of claim 9). *See, e.g.*, Pet. 80 (first fibers), 84–85 (second fibers), 87–89 (claim 2), 95–97 (claims 17 and 18); *see also id.* at 91–92 (claim 9).

Petitioner contends the first and second pluralities of fibers are disclosed in Chuter's graft/fabric-pile backing embodiment. Pet. 80, 84–85. Petitioner's annotated version of Chuter's Figures 2 and 3, reproduced below, illustrate Petitioner's contentions.



Pet. 85. According to Petitioner, Chuter's individual outwardly-extending fibers (green) in the fabric pile (orange) satisfy the first plurality of fibers; and fibers of the fabric pile backing (blue) satisfy the second plurality of fibers. *Id.* at 80, 84–85. For the "spacing" limitations, Petitioner contends

Chuter's fabric pile backing layer would preferably be "porous" and "at least some of the spacings between the fibers in the backing layer would extend to the frame." *Id.* at 87–88 (citing Ex. 1003 ¶ 278).

As with Petitioner's argument based on Spenser II above (*supra* Section III(E)), Petitioner contends a POSA would have been motivated to add Chuter's fiber pile to Spenser, and to replace Levi's outer skirt with the fiber pile to reduce PVL and promote tissue ingrowth. *Id.* at 81–83.

Petitioner's challenge here suffers from the same shortcomings as discussed above for the Spenser II-based grounds (Grounds 1 and 2). For claims 2, 17, and 18, the record is still wanting for a coherent construction of the "spacing" limitations that permits a comparison against the asserted art. Without such a construction, we are unable to determine whether the addition of Chuter's fiber backing layer to the valves of Spenser or Levi would satisfy the claims' "spacing" limitations. We are, thus, not persuaded that Petitioner is reasonably likely to prevail in establishing that at least one of claims 2, 17, or 18 are unpatentable based on the argument and evidence presently before us.

Nor are we persuaded that Petitioner is reasonably likely to prevail on its challenge to claim 9 relying on a modification of Spenser or Levi based upon Chuter's backing layer. As discussed above, claim 9 requires that the valve be free of a *non-porous* (i.e., fluid impermeable) graft covering between the first and second fibers and the frame. *See* Section III(E)(2). Petitioner argues Chuter's backing layer would "preferably be a porous material" to, for example, maximize compressibility. Pet. 92 (citing Ex. 1003 ¶ 295). Here, Petitioner appears to be using "porous" in a manner that refers to hypothetical "pores" in the Chuter backing layer. *See, e.g.*, *id.* at 88 (citing Norris and a "ground layer" having a "porosity that can provide

some space into which the loops . . . can be compressed").[23] This does not evidence that Chuter's backing layer would allow fluid to flow through it and thus be "porous" in the context of the '834 patent's disclosure and claims. Prelim. Resp. 55 (asserting "no disclosure in Chuter suggesting that its pile fabric backing is 'porous' and no spacings are shown or described in [the backing layer of] Chuter") (citing Ex. 1116, Figs. 1, 4). On this record, we find it more likely that Chuter's fabric pile backing would be understood as "non-porous" and, thus, claim 9's requirement that the valve be "free of" a non-porous covering is not met. Ex. 2002 (Brecker Decl.) ¶ 104 (testifying "the function of Chuter's fabric pile backing as taught requires it to be non-porous when implanted," and a POSA "would expect a TAVR's [(transcatheter aortic valve replacement)] outer cloth to be 'sufficiently dense' to prevent blood leakage" (citing, e.g., Buller's testimony (Ex. 2128 ¶ 222) in related proceedings).

b) Chuter Occluder Embodiment (all claims)

As an alternative, Petitioner cites Chuter's "embodiments without the 'backing layer'" and with individual fibers that extend both outwardly and inwardly from a frame. Pet. 80, 86, 88–89. Chuter's Figures 9 and 10, as annotated by Petitioner, are provided below.

[23] Norris is not advanced as part of the combination of asserted prior art in this matter. Moreover, even looking at the cited disclosure of Norris, it is not evident that any pores or "spaces" as contemplated pass through Norris's ground layer. Pet. 88; Ex. 1074, Fig. 1; Prelim. Resp. 44–45 (citing Ex. 1074, Fig. 2, 4:64–67) as teaching knitting the ground layer "with a uniform density" so "gaps and voids in the knit pattern ***can be avoided***").

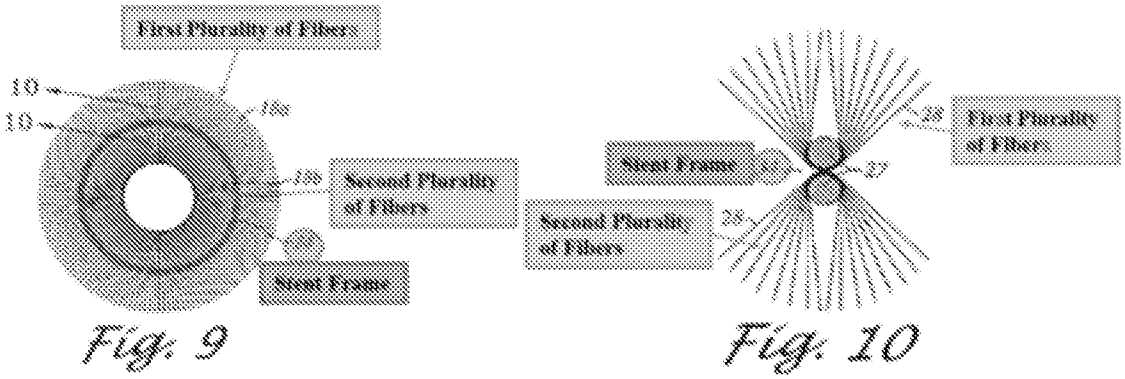


Fig. 9 Fig. 10

Id.; Ex. 1116, Figs. 9, 10. As shown above, Petitioner contends that the above embodiment of Chuter discloses a frame (red annotation) and first (green annotation) and second (blue annotation) pluralities of fibers as claimed. Pet. 86. Petitioner also argues that, in this embodiment, "Chuter illustrates spacings between inwardly-extending fibers . . . that extend to the frame."[24] *Id.* at 88–89 (citing Ex. 1116, Fig. 9, ¶ 57). Petitioner argues that a POSA "would have been motivated to add similar, bi-directional fiber piles to Spenser's and Levi's valves to ensure tissue ingrowth, blood coagulation, and formation of a seal between (1) the THV frame and native tissue, and (2) the THV frame and inner polymer covering." *Id.* at 86–87 (citing Ex. 1003 ¶ 274).

Considering the evidence of record, Petitioner's argument is unpersuasive. Petitioner sidesteps the fact that the cited Chuter embodiments without a backing layer and with the inwardly-directed fibers are described as addressing a different purpose—***occlusion*** of the blood vessel. *See, e.g.*, Ex. 1116 ¶¶ 5, 18, 57, Figs. 8–10. As argued by Patent Owner, "Chuter's occluder, used in a bypass procedure is intended to stop

[24] Concerns about the absence of a clear meaning for the claimed "spacing" remain for Chuter's occluder embodiment. But, we find that Petitioner has not met its institution burden for additional reasons, as explained here.

all blood from passing" and "is antithetical to a TAVR which is designed to allow blood to pass through the channel." Prelim. Resp. 58. Moreover, as explained by Dr. Brecker, "[t]he principal function of an occluder, including Chuter's occluder, is to 'prevent all blood flow into' a vessel." Ex. 2002 ¶¶ 108–111 (citing, e.g., Ex. 1116 ¶¶ 5, 18, 57). By contrast, "TAVRs, must leave the aorta (a large vessel) unobstructed to allow blood flow through the aortic artery and prosthetic leaflets." *Id.* We, thus, tend to agree with Dr. Brecker that "[i]t would, accordingly, be counterintuitive for a [POSA] to look to a device designed to occlude a blood vessel when designing a TAVR." *Id.* (testifying that "[n]o [POSA] would look to this [occluder] design when considering a TAVR valve and . . . would further have concerns about the pro-thrombotic potential of the arrangement of fibers in Chuter").

Patent Owner argues that "Chuter's occluder, is, fundamentally, ill-suited for the TAVR environment," such as relevant to the valves of Spenser or Levi. Prelim. Resp. 62. Here too, we tend to agree. Where a proposed combination would run counter to the primary reference's stated purpose, the POSA would not generally be motivated to make that combination. *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1069–70 (Fed. Cir. 2018). On this record, Petitioner provides "no explanation for how Chuter's [inwardly-extending] fibers would be adjusted to allow blood to pass unobstructed through the leaflets" and valves of Spenser or Levi. Prelim. Resp. 62. We are, therefore, unpersuaded that a POSA would have been motivated to add the features of Chuter's cited occluder embodiment to Spenser's or Levi's valves.

Looking at Chuter's Figure 9 might suggest an opening in the central aspect in which blood could readily flow through the device. Such an

interpretation would seem at odds, however, with the core purposes of an occluder (e.g., to "prevent all blood flow" and "form a fabric pile 'plug'"). Ex. 1116 ¶¶ 5, 57. Such interpretation would also run counter to Chuter's additional views of the occluder showing no material opening, especially when paired against figures depicting Chuter's graft embodiment having the backing layer and *without* the inner-disposed fibers, which embodiment expressly identifies an open longitudinal "lumen or bore" that "permit[s] blood flow." *Compare id.* at Figs. 8, 12, *with id.* at Figs. 2–3 (structure 20), ¶ 54.

Petitioner's assertions that POSAs had the skill to "optimize[]" fiber lengths and densities for endovascular delivery and proper sealing are conclusory and do not outweigh the evidence that detracts from the proposed motivation in the first instance, as discussed above. Pet. 84, 87; *InTouch Tech., Inc. v. VGO Comm., Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014) (finding hindsight bias in expert testimony that "primarily consisted of conclusory references to [the] belief that one of ordinary skill in the art could combine these references, not that they would have been motivated to do so"). In addition, Petitioner's unspecified modifications leave important questions unanswered. *Sisvel Int'l. S.A. v. Sierra Wireless, Inc.*, 82 F.4th 1355, 1364 (Fed. Cir. 2023) (affirming Board's rejection of obviousness rationales that "were too conclusory, lacked clarity, or suffered from both problems"); Prelim. Resp. 73–77. For example, Petitioner does not explain sufficiently and persuasively why (and how) Chuter's inwardly-extending fibers would be added to Spenser's frame. Petitioner contends such addition would ensure tissue ingrowth and sealing between the frame and inner polymer covering. Pet. 86–87 (citing Ex. 1003 ¶ 274). But, Spenser already teaches that a "strong sealing line" is formed between its frame, the inner

PET layers, and the leaflets by suturing those structures together at multiple points.[25] Ex. 1010, 26:40–48; *see supra* Section III(D)(1) (Fig. 44b (as annotated)). Adding Chuter's inner-disposed fibers along the inner-surfaces of Spenser's frame (e.g., between Spenser's frame and PET layer) would, thus, appear to be unnecessary or perhaps harmful. In short, Petitioner's non-specific assertions about adding and optimizing Chuter's inwardly-directed fibers look, on this record, like impermissible hindsight. Prelim. Resp. 61–62, 76–77; Ex. 2002 ¶ 110.

Lastly, the supposed "additional motivation" supplied by Spenser II for adding Chuter's fiber pile does not change the result here. Pet. 97. Petitioner contends that "Spenser II teaches the addition of compressible materials to the outside of THVs for preventing PVL." *Id.* (citing Ex. 1011 ¶ 145; Ex. 1003 ¶¶ 336–337). This rationale provides no persuasive support for adding the inwardly-extending fibers of Chuter's occluder embodiment to Spenser or Levi.

2. Conclusion

On this record and for the reasons above, Petitioner has not shown under Grounds 3–6 that it is reasonably likely to prevail in establishing that at least one of claims 2, 9, 17, and 18 would have been obvious over Spenser or Levi in further combination with Chuter (even considering the alleged "additional motivation" supplied by Spenser II).

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[25] Spenser may not have adequately addressed potential paravalvular leakage between the frame and a patient's native tissues—a problem Spenser II sought to address with its compressible material disposed along the outer surface of the stent. Ex. 1011 ¶¶ 10–11, 145, Fig. 22. But that does not (at least not on this record) identify a perceived problem with leakage between the frame and inner PET (alleged polymer) layer in the Spenser device.

IV. CONCLUSION

For the reasons explained above, Petitioner has not established a reasonable likelihood of prevailing on its assertion that at least one of the challenged claims is unpatentable based on the grounds advanced. This conclusion, however, is not a final determination as to the patentability of any challenged claim.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied*, and we do not institute *inter partes* review of any claim of the '834 patent based on the grounds asserted in this Petition.